K031065

JUN 23 2003

Syringex Safety Syringe®

510(k) Summary
21 CFR 807.92

Date of Summary Preparation: 3-29-2003

Submitter: Syringex Medical, Inc.
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Device Name

Proprietary Device (Trade) Name:	Syringex Safety Syringe®
Common Device Name:	Piston Syringe
Device Classification Name:	Syringe, Antistick
510(k) Number	K031065

Legally marketed device to which we claim equivalence:
SafeSnap Retractable Needle Syringe
U.S. Medical Instruments, Inc.
San Diego, CA 92127
510(k) Number K925039, K910520

Description of device
The Syringex Safety Syringe® is a retractable needle safety syringe. The syringe design employs a retractable mechanism that becomes engaged upon injection of the syringes contents. Withdrawal of the plunger retracts the needle into the syringe barrel, holding it securely in place. The plunger stem is broken off to prevent pushing the needle assembly forward. The syringe may be made in all sizes with needle gauges ranging from 18 to 30. The length of the needle is limited only by the length of the barrel in order to contain the needle. Available in lengths from 5/16" to 1 ½".

Intended Use
The Syringex Safety Syringe® is a sterile, non-toxic, non-pyrogenic, retractable needle, single use, disposable syringe for injecting fluids into or withdrawing fluids from the body while helping to provide protection from accidental needlestick injuries. The Syringex Safety Syringe® functions as a conventional hypodermic syringe except for its added ability to retract and contain the contaminated needle safely inside the syringe barrel immediately after the completion of the patient injection.

Summary of technological characteristics of device compared to the predicate device.
The Syringex Safety Syringe® is substantially equivalent to the previously marketed U.S. Medical SafeSnap syringe.

The SafeSnap allows Luer Lock needles to be interchanged. The Syringex Safety Syringe® is currently provided with a safety needle assembly permanently in place.

Both syringes are basically standard piston syringes with mechanisms that lock the needle assemblies to the end of the plungers when the plungers are fully depressed. The SafeSnap requires a hinged lock at the end of the barrel to be released after the plunger locks onto the needle assembly.

With both syringes, retracting the plunger pulls the needle assembly into the barrel and the plunger stems are broken off. The SafeSnap requires the broken plunger to be pushed into the other end of the syringe barrel to prevent the needle assembly from moving forward, and risk of exposing the needle sharp. The Syringex Safety Syringe® needle assembly is secured inside the barrel with a mechanism that snaps the needle assembly in place as the plunger is withdrawn. Alternately, the Syringex needle assembly may be configured so that the needle is canted to the side, additionally preventing it from sliding forward.

With the Syringex Safety Syringe® the needle can be withdrawn directly from the patient into the barrel, and the operation can be accomplished with a one handed technique. With the SafeSnap a hinged lock must be released with a second hand before the needle assembly can be withdrawn, potentially causing tissue trauma if an attempt is made to withdraw the needle directly from the injection site..

Both syringes employ plastic, rubber, stainless steel, adhesive, and a lubricant. All of the materials used by Syringex have passed Tripartite or ISO 10993 specifications. Biocompatibility and pyrogenicity testing and sterilization validation will be performed on complete Syringex Safety Syringes® after the assembly operation has been completed and before the syringes are released for use. We plan to use the limulus amebocyte lysate (LAL) Test method to determine that each lot is non-pyrogenic.

The "predicate" SafeSnap syringe is provided with needle gages from 20 to 29G and in lengths from ½ " to 1 ½ ". Syringex's Safety Syringe can be used with needles from 18 to 30G and in lengths from 5/16" to 1 ½ ".

Specific information about the SafeSnap other than what is contained in its shipping carton and on the individual pouches was unavailable, and U.S. Medical refused to supply any information in accordance with FDA requirements and FOI.

Discussion of Non-clinical (Bench) Tests to support equivalence
Both have transparent barrels. The Syringex barrel is 3.28" Long, .395" o.d. and .340" i.d. with a 3cc scale 2" long, marked at .1cc and numbers at ½ cc markings.
The SafeSnap barrel is 3.41" long, .467" o.d. and .38" i.d. with a 3cc scale 1.6" long marked at .1 cc and numbers at ½ cc markings.

Syringex has a maximum capacity of just over nominal +10%, the minimum required under ISO 7886-1. SafeSnap has about 53% more capacity than nominal, more than 5 times that required by ISO 7886-1.

Conclusions drawn from Non-clinical (Bench) tests
Bench testing to ISO 7886-1 has been conducted to examine compliance of both syringes. In all cases the Syringex Safety Syringe® was either equivalent to or exceeded the performance of the SafeSnap Syringe. In addition, design verification testing was conducted on the Syringex Safety Syringe® to confirm that the device met all functional specifications and applicable standards.

Although SafeSnap's barrel is .13" longer, Syringex has a longer scale and the marks are easier to read than Safesnap.

Syringex has a nominal engagement pressure just over 600 grams, while SafeSnap's engagement pressure is over 4200 grams. Thus SafeSnap is much more likely to cause tissue trauma when the safety feature is engaged.

Summary of Simulated Clinical Tests
In a simulated use study conducted at 3 hospitals and a veterinary center by a variety of doctors, nurses, physician's assistants and veterinarians, more than 60 investigators tested over 600 Syringex Safety Syringes® to evaluate the safety and effectiveness of the syringe by injecting fluids into an Injecta-Pad. All injections were successfully completed and 100% of the investigators had a positive response to the syringe evaluation and preferred it over the predicate. No injuries of any kind were reported.

The complete Statistical Analysis, Protocol and Questionnaires are attached as Exhibit B.

Conclusions and statistical summary of Simulated Clinical Tests
In all cases during the simulated clinical tests performed by healthcare professionals the Syringex Safety Syringe® was determined to be either equivalent to or exceeded the performance of the SafeSnap syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2003

Mr. John O. Jones
VP Operations, R & D
Syringex Medical, Incorporated
2311 Bear Hills Court
Draper, Utah 84020

Re: K031065
Trade/Device Name: Syringex Safety Syringe®
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF
Dated: June 15, 2003
Received: April 15, 2003

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031065

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Indications for Use

510(k) Number (if known): K031065

Device Name: **Syringex Safety Syringe®**

Indications for Use:

The primary intended use of the Syringex Safety Syringe® is "a hypodermic needle and syringe intended to inject fluid into or withdraw fluid from the body".

The secondary intended use is that the sharps safety feature will help to reduce the number of sharps injuries by providing an immediate and mandatory elimination of the sharp by its safe, simple and easy retraction into the barrel of the syringe. The feature will help prevent sharps injuries when using the device for its primary intended use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Patricia Cusenza

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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